UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 CIVIL ACTION: 01-CV-12257-PBS Judge Patti B. Saris
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	

PLAINTIFFS' OPPOSITION TO AMGEN INC.'S MOTION FOR A CONTINUED STAY OF DISCOVERY

Amgen's motion for a continued stay of discovery despite this Court's clear ruling allowing further discovery at the November 21, 2003 hearing, is a complete rehash of the 9(b) argument already before the Court. Amgen presents no unique circumstances justifying a stay. As to Amgen, plaintiffs complied with the Court's May 13 order. Thus, the AMCC sets forth the general AWP scheme and then as to Amgen as it does for every other defendant, it identifies "the specific drug or drugs that were purchased from the defendant [and] the allegedly fraudulent AWP for each drug," as required by the Court's May 12, 2003 Order. As explained in the voluminous briefing, and in response to the 23 separate memoranda which also raised this issue, plaintiffs have complied with 9(b) as applied by this Circuit in RICO cases where the fraud has occurred over a long period, and involves multiple acts the details of which have been actively concealed by defendants. The recent decision in *In re Lupron Marketing & Sales Practices*

Litig., MDL No. 1430 (D. Mass. Nov. 20, 2003)[1] fully supports plaintiffs' position that the AMCC satisfies 9(b) and belies Amgen's argument that a stay is appropriate because its motion is a "likely winner." In *Lupron* the court denied motions to dismiss RICO and state law claims arising out of the AWP scheme implemented by Abbott, TAP and others with respect to the drug Lupron. In doing so, the *Lupron* court rejected arguments identical to those now before the Court.

A. The Complaint's Allegations Against Amgen

1. Review of Amgen allegations

In the AMCC, Plaintiffs allege that Amgen, Inc. ("Amgen") engaged in an ongoing deliberate scheme to inflate the reported AWP of its drugs, utilize hidden rebates and financial inducements to its customers, and market the resulting spread to increase the market share of its drugs. *See* ¶¶ 217-30.[2] The AMCC states that Amgen has reported fraudulently inflated AWPs for six (6) drugs. *See* ¶ 217.[3]

In Appendix A to the AMCC, six drugs are identified for which plaintiffs allege Amgen has inflated the AWPs. The Appendix delineates each drug by manufacturer, product name, generic name, NDC number and fraudulent AWP for varying years. Further, Appendix B to the AMCC references those specific employee benefit plan plaintiffs that purchased any of the six drugs manufactured by Amgen.

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[1] Attached as Exhibit A.

[2] Unless otherwise indicated, "¶" references paragraphs in the AMCC.

[3] In a letter dated December 3, 2003, Amgen claims that three of these drugs are not reimbursable under Part B. Hence, under its view of discovery it is seeking a stay concerning three drugs. Those three drugs will soon be subject to discovery in the Montana case as there is no conceivable theory by which the *parens patriae* claims can be dismissed.

The AMCC further states that Amgen utilized hidden inducements to provide purchasers with substantial discounts in an effort to gain their patronage, but at the same time maintained the fiction of a higher wholesale price. *See* ¶ 226. In addition, Amgen deliberately concealed its fraudulent reporting and marketing of the AWP spread through rebates to at least its Epogen customers. *See* ¶ 220. This had the effect of lowering the true price charged. The government has documented inflated AWPs for both epoetin alfa and filgrastim, and Amgen's own public documents acknowledge that Amgen relies heavily on the reimbursement system to push or maintain market share for those products. ¶ 220.

Amgen, and other defendants, demand the type of detail that would turn the AMCC into a several thousand page document. Meanwhile, Amgen is on notice of the nature of these claims and indeed currently has an aggressive marketing program where it promotes the AWP spread. As the attached document (Exhibit B) reflects, Amgen is offering "off invoice" rebates to increase the spread. 30% is being offered for Aranesp while the AWP has not been reduced by 30%. In fact, it is offering "off invoice" discounts on other drugs as well. So Amgen is demanding a stay and more details while it knows full well what conduct is at issue. Plaintiffs should not be required to list this type of evidence for each drug or instance.

2. The Amgen-specific arguments lack merit

The main thrust of Amgen's argument, which is a repetition of its motion to dismiss, is that the AMCC's allegations may only be read to ascribe "guilt by association" to Amgen. This is not the case. The AMCC alleges that Amgen – a manufacturer that focuses on a few products all of which are reimbursable under Medicare Part B – systematically inflates the AWP for each of its few drugs in order to create profit incentives to providers for others in the drug distribution chain. Competitors for each of those drugs are identified because, as a matter of historic fact,

Amgen has gone toe-to-toe with these manufacturers (sometimes in highly acrimonious ways) to compete for market share, and in doing so has used the tool of AWP inflation (as has also been the case with its competitors). ¶¶ 222-23. And the GAO has reported that Epogen, one of Amgen's drugs, accounted for the second highest percentages of Medicare reimbursement and unlike most of the defendants, Amgen refused to provide GAO with information regarding rebates. ¶¶ 227-29. It is not unreasonable to infer from the information generally available, that disclosure of the rebates would have revealed AWP manipulation.

Moreover, while Amgen attacks the "logical inference" that Amgen has engaged in over-reimbursement as a corporate-wide mechanism to gain market share, Amgen ignores that it has endorsed this corporate practice and acknowledged it in litigation regarding its over-reimbursement policies. In *Amgen, Inc. v. Scully*, 234 F. Supp. 2d 9 (D.D.C. 2002), Amgen filed suit against HHS attacking a proposed HHS rule that would take reimbursement for Amgen's Aransep out of the AWP system and put it into a direct "pass-through" regime. The proposed regulation would not, of course, inhibit Amgen in any way with respect to the actual prices it could charge its customers. Nor did it affect Amgen's customers' ability to negotiate actual purchase prices with Amgen. Instead, the proposed regulation simply would affect the manner in which Amgen's customers would be reimbursed by Medicare for their Aransep purchases. (Meanwhile, one of Amgen's archrivals, Ortho Biotech Products, LP, a subsidiary of Johnson & Johnson and manufacturer of Procrit, also sought to intervene in the case; it, too, saw a significant competitive edge to seeking to enforce the proposed regulation which would give Amgen a disadvantage, and Ortho an advantage, in marketing the spread for reimbursement dollars in this competitive therapeutic category.) Amgen argued that it nevertheless had standing to complain.

The *Amgen* court rejected Amgen's argument, stating that it "appears to the Court that the interest plaintiff [was] seeking to protect is its own competitive interest in financial gain." *Id.* at 21. The Court then cited to *TAP Pharms. v. United States HHS*, 163 F.3d 199 (4th Cir. 1998) (in which TAP, the manufacturer of Lupron who eventually paid $875 million for its abusive trade pricing practices, attacked proposed HHS reimbursement charges for Lupron), and observed that Amgen's arguments – in an effort to protect its over-reimbursement marketing strategies – were identical to the interests that TAP sought to protect in *TAP Pharmaceuticals*:

> Like the drug manufacturer plaintiff in *TAP Pharmaceuticals,* Amgen asserts an interest in enforcing a statutory provision that purportedly sets the Medicare payment rate for a particular pharmaceutical product on the basis of 95 percent of the average wholesale price of that product, and not on the basis of the Medicare payment rate for a competing pharmaceutical product. Like the plaintiff in *Tap Pharmaceuticals,* Amgen is asserting purely commercial interests in increasing its revenues and preventing loss of market share to its competitor. Like the plaintiff in *TAP Pharmaceuticals,* Amgen is neither a beneficiary of the Medicare statute nor a competitor of an entity that is regulated by that statute . . . Since its purely commercial interest in the sale of Aransep does not place it "in the same position as a member" of the beneficiary group or "a commercial competitor of such a member," Amgen, like the plaintiff in *TAP Pharmaceuticals*, cannot satisfy the prudential standing requirements imposed by the APA. [*Amgen*, 234 F. Supp. 2d at 24.]

Again it is reasonable to infer that Amgen would not be complaining, to the point of launching litigation, if it were not using the AWP scheme to its advantage.

B. The Complaint Satisfies 9(b) Under First Circuit Authority and the *Lupron* Decision

In the *Lupron* litigation plaintiffs brought claims against Abbott Laboratories and others alleging violations of RICO and state law arising out of the same AWP scheme at issue here.

Defendants moved to dismiss claiming that plaintiffs have failed to "set forth the time, place, content, or individuals responsible for the mail or wire fraud" and rely instead on "generic assertions that marketing, sales and other documents were disseminated by wire." *Lupron* at 20.

The *Lupron* court found that the complaint, which is similar to the AMCC, satisfied 9(b):

> [T]he Amended Complaint alleges a course of protracted conduct on the defendants' part that virtually spanned the ten years from the introduction of Lupron® to the American market to TAP's guilty plea in 2001. It is true, as defendants contend, that the Amended Complaint does not identify specific instances of mailings, or the use of facsimile transmissions, or the telephone. But the Amended Complaint is reasonably specific as to the nature of the materials that are alleged to have been distributed in furtherance of the scheme. *See, e.g.*, Consolidated Complaint ¶ 88 (1996 fraudulent marketing materials), ¶ 108 (1995 fraudulent sales directives), ¶ 150 (national marketing and sales plans). More particularly ¶ 151 specifies eight categories of documents that are alleged to have been disseminated by mail or wire in furtherance of the scheme, including: (1) marketing materials promoting the AWP spread; (2) the submissions of the AWP to the *Red Book*; (3) communications related to the distribution of free samples; (4) inaccurate credit memos and invoices sent to physicians; (5) communications regarding junkets and the TAP into the Future program; (6) communications with government agencies misrepresenting the AWP; (7) similar misleading communications with patients and health insurers; and (8) the receipt of payments for Lupron®.[4]

The AMCC makes nearly identical types of allegations. The AMCC identifies the nature of the materials alleged to be part of the AWP scheme in the same general fashion as did the *Lupron* plaintiffs. *See, e.g.*, ¶¶ 160-63 (publication of AWPs), ¶¶ 164-66 (free samples), ¶ 167 (inducements), ¶¶ 170-78 (secret deals with PBMs), ¶¶ 191-96 (concealment of the scheme). And, as did the plaintiffs in *Lupron*, the AMCC at ¶ 666 then identifies nine categories of documents used to further the scheme:

[4] *Lupron* at 22 (footnote omitted).

(a) Marketing materials about the AWPs for brand name drugs and the available spread, which were sent by the Defendant Drug Manufacturers to PBMs (including Medco Health) located across the country;

(b) Written representations of the AWPs made by the Defendant Drug Manufacturers to the Publishers, which were made at least annually and in many cases several times during a single year;

(c) Thousands of written and oral communications discussing, negotiating and confirming the placement of a Defendant Drug Manufacturer's drugs on a particular PBM's formulary;

(d) Documents providing information or incentives designed to lessen the prices that each of the PBMs paid for drugs, and/or to conceal those prices or the AWP Scheme;

(e) Written communications, including checks, relating to rebates, kickbacks or other financial inducements paid to each of the PBMs to persuade them to advocate one Defendant Drug Manufacturers' drug over a drug manufactured by a competitor;

(f) Written and oral communications with U.S. Government agencies and private insurers that fraudulently misrepresented what the AWPs were, or that were intended to deter investigations into the true nature of the AWPs or to forestall changes to reimbursement based on something other than AWPs;

(g) Written and oral communications with health insurers and patients;

(h) Receipts of money on tens of thousands of occasions through the U.S. mails and interstate wire facilities – the wrongful proceeds of the Defendant Drug Manufacturers' AWP Scheme; and

(i) In addition to the above-referenced RICO predicate acts, Defendants' corporate headquarters have communicated through use of the U.S. mails and by interstate wire facilities with their various local headquarters or divisions, in furtherance of the AWP Scheme.

Thus, the AMCC has at least the same level of particularity if not more than that deemed sufficient in *Lupron*. And, in fact, there is more to the AMCC allegations regarding Amgen. The AMCC cites to a 1993 OIG Report which detailed how Amgen gave substantial year-end rebates to its customers based on their purchases of Epogen. The report noted that Medicare and Medicare beneficiaries did not receive the benefit of any rebates; all monies remained with the provider. ¶ 225. And unlike other defendants, Amgen acted to affirmatively conceal its AWP manipulation when it ***flatly refused to respond to an OIG request to provide relevant data***. ¶ 228.[5] Again this adds support to the inferences plaintiffs are entitled to a motion to dismiss.

After finding the foregoing allegations sufficient, the Court in *Lupron* concluded as follows:

> But whether or not the Amended Complaint is faithful in very [sic] respect to the requirements of Rule 9(b), a dismissal for failure to comply with the Rule at this point in the litigation would be inappropriate.
>
> > [I]n a RICO mail and wire fraud case, in regards to the details of just when and where the mail or wires were used, we hold that dismissal should not be *automatic* once the lower court determines that Rule 9(b) was not satisfied. In an appropriate case, where, for example the specific allegations of the plaintiff make it likely that the defendant used interstate mail or telecommunications facilities, and the specific information as to use is likely in the exclusive control of the defendant, the court should make a *second* determination as to whether the claim as presented warrants the allowance of discovery and if so, thereafter provide an opportunity to amend the defective complaint. We advocate this procedure because of the apparent difficulties in specifically pleading mail and wire fraud as predicate acts. In the instant case, it is

[5] In effect, Amgen wants to be rewarded for its concealment of its AWP manipulation. Other defendants cooperated with the OIG and plaintiffs have thus more detailed allegations as a result of data being released. Amgen, by its refusal to release the data, now wants to use its concealment as a shield from these claims.

> seemingly impossible for the plaintiff to have known exactly when the various defendants phoned or wrote to each other or exactly what was said. The plaintiff clearly set out a general scheme, which very plausibly was meant to defraud the plaintiff, and also probably involved interstate commerce. Assuming the facts as stated in plaintiff's complaint, defendant Monarch Investments is incorporated in a different state than that resided in by the other defendants. In this day and age, it is difficult to perceive how the defendants would have communicated without the use of the mail or interstate wires. *See Federal Deposit Insurance Corp. v. Kerr*, 637 F. Supp. at 835 ("... it is hard to imagine how such a transaction could be carried out without the use of such interstate devices.").

> *Becher*, 829 F.2d at 290-291. If, for example, I take the most telling of the acts of alleged fraud, TAP's publication in the *Red Book* of the inflated AWP during the years 1992 to 2000, it is possible that TAP was prescient enough to rely solely on bicycle messengers (or verbal communications as defendants suggest) to communicate with the publishers, but I doubt it. The suggestion is improbable enough to permit plaintiffs an opportunity to rectify any deficiencies in the Amended Complaint in this regard upon the completion of discovery.

Lupron at 23-24 (emphasis in original).

The same rationale applies here, even more so, where Amgen has refused to even provide the information as to the particulars of the scheme when asked to do so by Congressional investigators.

C. Amgen Does Not Have a "Likely Winner"

Amgen claims that its motion to dismiss is a "likely winner." Amgen at 3. However, the *Lupron* decision suggests the opposite on every basis that was asserted by Amgen as a basis for dismissal. After denying the 9(b) motions, the Court in *Lupron* then denied the challenge to the RICO enterprise, and found that the complaint had alleged, "some part in directing the affairs of

the enterprise" sufficient to satisfy the *Reeves* test. *Lupron* at 25.[6] And the Court upheld the enterprise using the following analogy:

> The basic idea is that while one basketball player does not constitute a team, an association of five players does, without each losing his identity as a distinct person. In *Odishelidze* (and *Schofield*), only one entity was said to have filled the dual function of person and enterprise. That is not the case where, as here, the enterprise is aid to be the collective whole of its constituent parts.[7]

The publisher and PBM enterprises each fit the basketball team analogy perfectly.[8] Each member of the association in fact enterprise is a distinct entity, but together they have formed a team as far as the AWP scheme is concerned, and that team has as a common goal, the use of AWP as a reimbursement benchmark throughout the drug distribution system.

The *Lupron* court also rejected a virtually identical causation defense to that raised here:

> RICO requires "some direct relation between the injury asserted and the injurious conduct alleged." *Holmes*, 503 U.S. at 268. Defendants challenge to this element of plaintiffs' RICO claims borders on the frivolous. The argument begins with a settled principle of law, that the intervening act of a third party can break the chain of proximate causation thereby relieving the original actor of liability. *Griffiths v. Campbell*, 425 Mass. 31, 34-36 (1997). The intervening third party actors to whom defendants refer are the physicians who purchased and prescribed Lupron®. ... ***What the argument ignores is the corollary requirement that the intervening act be unforeseeable and completely independent of any act undertaken by the original actor.*** (An arsonist, for example, is not relieved of liability by a fireman's intervening efforts to suppress the fire). *See Massachusetts Superior Court Civil Jury Instructions* § 2.1.9 (1998). A proximate cause need not be a precipitating or "but for" cause, in the sense of being the last cause in a chain of events leading to the harm, but need only be a

[6] Plaintiffs here, as did plaintiffs in *Lupron*, alleged that *Reeves* does not apply, under *United States v. Oreto*, 37 F.3d 739, 751 (1st Cir. 1994) and *United States v. Owens*, 167 F.3d 739, 754 (1st Cir. 1999) where the defendants are enterprise insiders. The *Lupron* court did not decide this issue as it found *Reeves* to have been satisfied. *Lupron* at 26.

[7] *Lupron* at 27.

[8] The *Lupron* court dismissed the physician enterprise for similar reasons as this Court did in its ruling on the MCC.

> substantial cause of a succession of events that in a logical sequence ultimately causes a plaintiff injury. *Id.* § 2.1.8. Here it was defendants who instigated both the culpable and the innocent intermediaries to commit acts that were not only foreseeable but intended. By way of analogy, a company that issues its stock at a fraudulently inflated price is not insulted [sic] from liability by the intervening acts of the brokers, transfer agents, and financial analysts who promote the sales of its stock, execute trades on behalf of injured investors, and report the company's falsified financial statements. ***Plaintiffs' allegations that as a result of the Lupron® marketing scheme they were induced to make many millions of dollars in overpayments for the drug is more than sufficient to satisfy RICO's causation requirement at the pleading stage.*** *National Organization for Women, Inc. v. Scheidler*, 510 U.S. 249, 256 (1994).[9] (Emphasis added.)

Finally, the *Lupron* court rejected an attempt to dismiss the state consumer protection claims. *Lupron* at 40-41. Based on *Lupron*, Amgen's argument that it has a "likely winner" of a motion to dismiss that justifies a stay is seriously flawed.

II. CONCLUSION

For all the foregoing reasons, as well as those expressed in plaintiffs' responses to the motions to dismiss, Amgen's motion should be denied.

DATED: December 3, 2003.

Respectfully submitted,

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[9] *Lupron* at 30-31.

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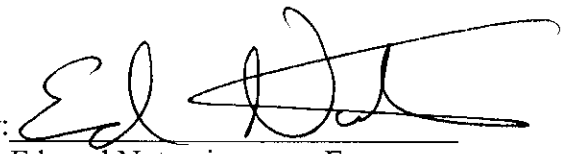
CERTIFICATE OF SERVICE

I hereby certify that I, Edward Notargiacomo, an attorney, caused true and correct copies of the foregoing Plaintiffs' Opposition to Amgen Inc.'s Motion for a Continued Stay of Discovery to be served on all counsel of record electronically, pursuant to Section D of Case Management Order No. 2., this 4th day of December 2003.

By: 

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